Pliant Therapeutics Provides Corporate Update and Reports Third Quarter 2023 Financial Results

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Positive interim 12-week safety and efficacy data reported from Phase 2a INTEGRIS-PSC trial in patients with PSC

Positive DSMB safety review recommends INTEGRIS-PSC trial continue without modification

Key Clinical Development and Regulatory appointments expand leadership team

SOUTH SAN FRANCISCO, Calif., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Pliant Therapeutics, Inc. (Nasdaq: PLRX), a clinical-stage biotechnology company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases, today provided a corporate update and reported third quarter 2023 financial results.

"The third quarter was highlighted by positive interim data from the INTEGRIS-PSC trial of bexotegrast demonstrating a favorable safety profile and encouraging antifibrotic activity in PSC. Coupled with positive data reported from INTEGRIS-IPF, these data illustrate the broad potential of bexotegrast in fibrotic diseases across multiple organ systems," said Bernard Coulie, M.D., Ph.D., President and Chief Executive Officer of Pliant Therapeutics. "Our pipeline continues to advance, led by the ongoing enrollment of our Phase 2b BEACON-IPF trial. We have also taken active steps to strengthen our leadership team with the appointments of Minnie Kuo as Chief Development Officer and Mishima Gerhart as Chief Regulatory Officer, coming at an important time in Pliant's evolution into a late-stage clinical development company."

Third Quarter and Recent Highlights

Bexotegrast Highlights

- **Enrollment continues in BEACON-IPF, a Phase 2b trial of bexotegrast in patients with idiopathic pulmonary fibrosis** (**IPF).** BEACON-IPF is a 52-week, multinational, randomized, dose-ranging, double-blind, placebo-controlled trial evaluating bexotegrast at once-daily doses of 160 mg or 320 mg. BEACON-IPF is expected to enroll approximately 270 patients with IPF.
- **Positive safety and efficacy data from INTEGRIS-PSC Phase 2a trial in patients with primary sclerosing cholangitis (PSC).** At once-daily doses of 40 mg, 80 mg and 160 mg, bexotegrast was well tolerated over 12 weeks of treatment with no drug-related severe or serious adverse events. At all doses tested, bexotegrast reduced both Enhanced Liver Fibrosis (ELF) scores and PRO-C3 levels at Week 12 relative to placebo, with statistically significant differences at the 160 mg dose. These data were selected for an oral late-breaker presentation at next week's American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting ® 2023.
- **Positive independent Data Safety Monitoring Board (DSMB) review of the ongoing of INTEGRIS-PSC Phase 2a trial.** This regularly scheduled DSMB review was held in October after the completion of enrollment of the 320 mg dose cohort. The DSMB examined the safety data from all patients enrolled, with all patients completing at least 12 weeks of treatment, and recommended the INTEGRIS-PSC trial continue without modification.
- **INTEGRIS-PSC interim 12-week 320 mg dose data expected in the first quarter of 2024.** This trial is evaluating the safety, tolerability and pharmacokinetics of bexotegrast at 320 mg versus placebo at 12 and 24 weeks of treatment in approximately 28 patients with PSC. The trial is also evaluating exploratory efficacy endpoints including fibrosis biomarkers such as serum PRO-C3 and ELF score, changes in alkaline phosphatase (ALP) and liver imaging. Twenty-four week data from the 320 mg dose group is expected in mid-2024.

Pipeline Programs

- **Phase 1 trial of PLN-101095 in solid tumors is enrolling.** This is a Phase 1 open-label trial of PLN-101095, an oral, small-molecule, dual selective inhibitor of αvβ8 and αvβ1 integrins designed to block TGF-β activation in the tumor microenvironment. This trial is enrolling patients with solid tumors that are resistant to immune checkpoint inhibitors.
- **Muscular dystrophy program on track for regulatory filing in the first quarter of 2024.** PLN-101325 is a monoclonal antibody designed to act as an allosteric agonist of integrin α7β1. Filing for first-in-human clinical studies in Duchenne muscular dystrophy (DMD) is expected in the first quarter of 2024.

Corporate Highlights

- **Appointment of Minnie Kuo as Chief Development Officer**. Ms. Kuo is an experienced biopharma executive hired to oversee all clinical and non-clinical development activities.

- **Appointment of S. Mishima Gerhart as Chief Regulatory Officer** Ms. Gerhart is a recognized leader in the biotechnology and pharmaceutical industries hired to lead all regulatory activities and quality functions.

Third Quarter 2023 Financial Results

- Research and development expenses were $32.3 million, as compared to $24.6 million for the prior-year quarter. The increase was due primarily to higher employee-related expenses and increased clinical and manufacturing-related costs associated with our lead program, bexotegrast, partially offset by a decrease in preclinical manufacturing costs for our pipeline product candidates.
- General and administrative expenses were $15.3 million, as compared to $8.8 million for the prior-year quarter. The increase was due to higher employee-related expenses.
- Net loss of $41.5 million as compared to $30.6 million for the prior-year quarter due to an increase in operating expenses coupled with a decrease in collaboration revenues under the Novartis collaboration during the quarter.
- As of September 30, 2023, the Company had cash, cash equivalents and short-term investments of $523.6 million which the Company expects to be sufficient to fund operations into the second half of 2026.

About Pliant Therapeutics, Inc.

Pliant Therapeutics is a clinical-stage biopharmaceutical company and leader in the discovery and development of novel therapeutics for the treatment of fibrotic diseases. Pliant's lead product candidate, bexotegrast (PLN-74809), is an oral, small molecule, dual selective inhibitor of αvß6 and αvß1 integrins that is in development in the lead indications for the treatment of idiopathic pulmonary fibrosis, or IPF, and primary sclerosing cholangitis, or PSC. Bexotegrast has received Fast Track Designation and Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in IPF and PSC and Orphan Drug Designation from the European Medicines Agency in IPF and PSC. Pliant has initiated BEACON-IPF, a Phase 2b trial of bexotegrast in IPF. Pliant has also developed PLN-1474, a small molecule, selective inhibitor of αvß1 integrin for the treatment of nonalcoholic steatohepatitis, or NASH with liver fibrosis. Pliant has initiated a Phase 1 study for its third clinical program, PLN-101095, a small molecule, dual-selective inhibitor of αvß8 and αvß1 integrins, that is being developed for the treatment of solid tumors. In addition to clinical-stage programs, Pliant currently has a preclinical program targeting muscular dystrophies. For additional information, please visit: www.PliantRx.com. Follow us on social media: X, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those regarding the safety, tolerability, pharmacodynamics and therapeutic potential of bexotegrast; our plans for the future development of bexotegrast, PLN-101325 and PLN-101095; bexotegrast's potential to become a treatment for IPF or PSC; the anticipated timing of data and progress from our clinical studies; discussions with regulatory authorities and the sufficiency of our cash runway to fund operations into the second half of 2026. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Pliant Therapeutics could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including those related to the development and commercialization of our product candidates, including any delays in our ongoing or planned preclinical or clinical trials, the impact of current macroeconomic and marketplace conditions, including the effects of COVID-19, on our business, operations, clinical supply and plans, our reliance on third parties for critical aspects of our development operations, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, including the availability of additional term loans under our loan facility, and our ability to obtain and maintain intellectual property protection for our product candidates. These and additional risks are discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Quarterly Report on Form 10-Q for the period ended September 30, 2023 which we are filing with the SEC today, available on the SEC's website at www.sec.gov. Unless otherwise noted, Pliant is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

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Pliant Therapeutics, Inc.
Condensed Statements of Operations
(Unaudited)
(In thousands, except number of shares and per share amounts)

	Three Months Ended September 30,	
	2023	**2022**
Revenue	$ —	$ 1,482
Operating expenses:		
Research and development	(32,339)	(24,606)

General and administrative	(15,346)	(8,823)
Total operating expenses	(47,685)	(33,429)
Loss from operations	(47,685)	(31,947)
Interest and other income (expense), net	6,515	1,633
Interest expense	(317)	(301)
Net loss	$ (41,487)	$ (30,615)
Net loss attributable to common stockholders	$ (41,487)	$ (30,615)
Net loss per share, attributable to common stockholders - basic and diluted	$ (0.70)	$ (0.65)
Shares used in computing net loss per share attributable to common stockholders - basic and diluted	59,688,451	46,799,058

Pliant Therapeutics, Inc.
Condensed Balance Sheets
(Unaudited)
(In thousands)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 57,679	$ 33,685
Short-term investments	465,933	297,502
Accounts receivable	—	1,983
Tax credit receivable	83	83
Prepaid expenses and other current assets	10,640	7,058
Total current assets	534,335	340,311
Property and equipment, net	3,969	4,486
Operating lease right-of-use assets	1,768	5,422
Other non-current assets	392	394
Total assets	$ 540,464	$ 350,613
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,360	$ 1,580
Accrued research and development	13,664	11,218
Accrued liabilities	8,310	8,658
Lease liabilities, current	2,061	2,457
Total current liabilities	27,395	23,913
Lease liabilities, non-current	—	3,429
Long-term debt	10,021	9,929
Total liabilities	37,416	37,271
Stockholders' equity		
Common stock	6	5
Additional paid-in capital	963,588	653,707
Accumulated deficit	(458,639)	(338,412)
Accumulated other comprehensive loss	(1,907)	(1,958)
Total stockholders' equity	503,048	313,342
Total liabilities and stockholders' equity	$ 540,464	$ 350,613